

K021547

JAN 24 2003

510 (k) Summary

Submitter: Jotec GmbH
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Contact Person: Dr. Ralf Kaufmann

Date Summary Prepared: May 9th, 2002

Trade or Proprietary Name: Jotec® FlowLine™ Bipore ePTFE Vascular Graft

Common or Usual Name: ePTFE Vascular Graft

Classification Name: Prosthesis, vascular graft of 6 millimeters or greater diameter

Predicates: Impra and Gore-Tex® and ePTFE vascular grafts.

Device Description:

The Jotec FlowLine Bipore ePTFE Vascular Graft is a tube composed of pure expanded polytetrafluoroethylene (ePTFE). The graft may also have an external line or other orientation mark and may also have an external FEP double helix support.

The Jotec FlowLine Bipore ePTFE Vascular Graft is composed of pure expanded polytetrafluoroethylene (ePTFE), as are the predicate devices. Like the predicate devices, the Jotec FlowLine Bipore ePTFE Vascular Graft may have an external support, and an external line or other orientation mark.

Non-clinical bench testing, as prescribed by the FDA Guidance Document for Vascular Graft Prostheses 510(k) Submissions demonstrated through mechanical testing and material analysis that the Jotec FlowLine Bipore ePTFE Vascular Graft is substantially equivalent to the predicate devices.

Statement of Intended Use:

The Jotec FlowLine Bipore ePTFE Vascular Graft is indicated in cases of arterial vasoreconstruction, primarily in the peripheral vascular region. It can also be used in extraanatomical reconstruction – femorofemoral and axillofemoral. Standard wall FlowLine Bipore ePTFE Vascular Grafts are also indicated for use as arteriovenous shunt prostheses in hemodialysis.

Substantial Equivalence Conclusion:

Mechanical and chemical tests, including material strength and chemical identification of the materials demonstrate that the FlowLine Bipore ePTFE Vascular Graft and predicate Gore-Tex® and Impra, Inc, ePTFE vascular grafts are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2003

Jotec GmbH
c/o Mr. Bruce Ruefer
Bridger Biomed
2430 N. 7th Avenue, Suite 4
Bozeman, MT 59715

Re: K021547
Jotec GmbH Flowline™ Bipore ePTFE Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: November 5, 2002
Received: November 6, 2002

Dear Mr. Ruefer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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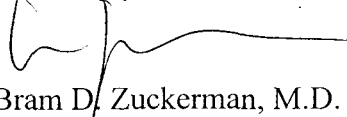
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address

<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health


Enclosure



10 Statement of Indication for Use

Indication for Use:

The Jotec FlowLine Bipore ePTFE Vascular Graft is indicated in cases of arterial vaso-reconstruction, primarily in the peripheral vascular region. It can also be used in extraanatomical reconstructions – femorofemoral and axillofemoral.

Standard Wall FlowLine Bipore ePTFE Vascular Grafts are also indicated for use as arteriovenous shunt prostheses in hemodialysis.



(Division of) 
Division of  Medical Devices
510(k) Number 14021547

Prescription Use X
(Per 21 CFR 801.109)